REMARKS

Claims 115 and 116 are amended and claims 40-42 and 46-48 are canceled. Claims 1, 15-28, 31-35, 37-39, 43-45, 49-52, 55-63, 67, 69-75, 79-108, 110-112, 115-117, 123-256, 272, 319-362, 365-373, 376, 377, 379-391, 393 and 394 are currently pending in the case. Claims 28, 31-35, 37-39, 43-45, 49-52, 55-63, 69-71, 90-93, 101, 103-108, 136-179, 183-216, 218, 243-250, 256, 319-322, 325, 328-342, 357-359 and 386-388 are withdrawn from consideration. Further examination and reconsideration of the presently claimed application are respectfully requested.

Request for Reinstatement of Withdrawn Claims 69-71 and 319-321

In the communication filed by the Applicant on August 19, 2010, claims 69-71 were inadvertently identified as being withdrawn. Applicant requests that the claims be reinstated, since they are directed to elected Invention I of a paint comprising an esterase of EC 3.1.8 and are generic to each of the other species elected for the captioned case.

The Examiner states on page 2 of the Office Action that "Claims 319-321 are herein withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions." The Applicant respectfully traverses that claims 319-321 are drawn to nonelected inventions. In particular, as set forth in detail below, claims 319-321 are generic or specific to each of the following species elected for the captioned case (which were elected in the communication filed January 30, 2009 by the Applicant in response to the restriction requirement issued October 31, 2008):

- a paint comprising an esterase of EC 3.1.8 (denoted in the restriction requirement dated October 31, 2008 as "Invention I");
- an enzyme of subclass designated by EC 3.1.8.1;
- an organophosphorus hydrolase comprising a *Flavobacterium sp opd* gene product;
- a structural analog of an organophosphorus hydrolase comprising a Co^{2+} ion at the enzyme active site;
- film formation at -10°C – 40°C/ambient conditions;

- liquid/solvent component of water;
- without any inorganic compounds;
- without any organic components;
- a thermoplastic binder;
- no plasticizer; and
- a combination of a filler and a preservative, wherein the preservative is a bactericide.

Since claims 319-321 are generic or specific to each of the aforementioned species, it is asserted that independent claims 319-321 are directed to elected inventions. For at least these reasons, the Applicant requests that claims 319-321 be reinstated.

Independent claim 319 includes a Markush-type limitation which lists particular types of coatings, specifically an architectural coating, an automotive coating, a can coating, a chemical agent resistant coating, a camouflage coating, a traffic marker coating, and an aircraft coating, all of which are inclusive to paints of those specified coating types. Thus, it is asserted that independent claim 319 is drawn to and, more specifically, is generic to the elected invention of a paint comprising an esterase of EC 3.1.8 (denoted in the restriction requirement dated October 31, 2008 as "Invention I"). Dependent claim 320 includes a Markush-type limitation listing particular types of paints and, thus, is specific to "Invention I". Claim 321 does not specifically denote types of paints, but claim 321 is dependent from claim 320 and, thus, is specific to "Invention I" for the same reason as claim 321. In addition to being directed to elected Invention I, claims 319-321 are generic to each of the other species elected for the captioned case (i.e., an enzyme of subclass designated by EC 3.1.8.1, an organophosphorus hydrolase comprising a *Flavobacterium sp opd* gene product, a structural analog of an organophosphorus hydrolase comprising a Co^{2+} ion at the enzyme active site, film formation at -10°C – 40°C/ambient conditions, liquid/solvent component of water, without any inorganic compounds, without any organic components, a thermoplastic binder, no plasticizer, and a combination of a filler and a preservative, wherein the preservative is a bactericide). As such, claims 319-321 are directed to an elected invention.

It is noted that in addition to the coating types recited in independent claim 319 the Markush-type limitation in independent claim 319 lists an elastomer, an adhesive, a sealant and a wax. The Applicant notes that per MPEP 803.2, Markush-type claims may include elected and non-elected subject matter and further must be examined at least with regard to the elected subject matter and, thus, are not required to be canceled, withdrawn or amended to remove non-elected subject matter. Consequently, it is not proper to require the withdrawal of claims 319-321 on the basis that independent claim 319 is directed at the nonelected subject matter of an elastomer, an adhesive, a sealant and a wax.

> A Markush-type claim may include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. … Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. *MPEP 803.2*

Double Patenting Rejection

Claims 1, 15-27, 67, 72-75, 79-89, 94-100, 102, 110-112, 115-117, 123-135, 180-182, 217, 219-242, 251-255, 272, 323, 324, 326, 327, 343-356, 360-362, 365-373, 376, 377, 379-385, 389-391, 393 and 394 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-109 of U.S. Patent Application No. 12/474,921. To expedite prosecution, a terminal disclaimer is submitted in a separate paper to obviate the double patenting rejection in accordance with 37 C.F.R. § 1.321(c). Accordingly, removal of all the double patenting rejection is respectfully requested. It is noted that the Applicant intended to file a terminal disclaimer to obviate this rejection in response to the Office Action mailed February 19, 2010 and indicated so in the communication filed on August 19, 2010 (see, pg. 40 of the communication), but the terminal disclaimer was inadvertently omitted with the submission of the communication. The error is further evidenced in that the terminal disclaimer submitted with the current communication is dated August 19, 2010, the date of

submission of the previous communication. Applicant sincerely apologizes for the mistake and any confusion it may have caused.

Section 112, 2nd Paragraph, Rejection

Claims 21-27 were rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner deems the phrases "functional equivalent," "structural analog," and "sequence analog" indefinite for reasons described in the Office Action dated February 19, 2010. The Applicant respectfully traverses the rejection of the pending claims and maintains the arguments presented in the communication filed August 19, 2010 by the Applicant. The arguments are incorporated by reference as if fully set forth herein, but all have not been reiterated below for the sake of brevity. The Examiner responds to some of the arguments in the current Office Action in support of her position to maintain the rejection. Such responses are paraphrased below along with rebuttals by the Applicant. Further to the arguments set forth below, the Applicant notes that claims 18 and 19 include the term "functional equivalent" but yet were not rejected for indefiniteness in the current Office Action. Clarification is requested regarding whether this was on oversight or if the Examiner finds the use of the term in the context of those claims definite.

In the communication filed on August 19, 2010 by the Applicant, the Applicant set forth that claims 21-27 meet "Requirement A" of the second paragraph of 35. U.S.C. 112 since there has been no contentions or admissions contained in remarks filed by the Applicant or in affidavits filed under 37 CFR 1.132 which would render the subject matter recited in claims 21-27 to not correspond in scope with that which is regarded as the invention. In response, the Examiner acknowledges that no such remarks have been made, but contends remarks are not required to support the rejection because the "Applicants have not clearly disclosed what is regarded as the invention for the phrases "functional equivalent," "structural analog" and "sequence analog"." (Office Action, pg. 7). Furthermore, the Examiner acknowledges the requirement in view of *In re Moore* case law that in the absence to evidence to the contrary, the invention set forth in the claims must be presumed to be that which applicants regard as their

invention (Office Action, pg. 6), but then dismisses the requirement based on the assertion that "neither the claims [nor] the specification distinctly disclose the subject matter which the applicant regards as the invention." (Office Action, pg. 7).

It is asserted that such dismissal is improper based on the patent examining guideline clearly set forth in MPEP 2172 that a rejection based on the failure to satisfy "Requirement A" of the second paragraph of 35. U.S.C. 112 is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims (*see*, MPEP 2172, I. Focus the Examination, underline added for emphasis). Since there has been no contentions or admissions contained in remarks filed by the Applicant or in affidavits filed under 37 CFR 1.132 which would render the subject matter recited in claims 21-27 to not correspond in scope with that which is regarded as the invention, the Applicant maintains the assertion that claims 21-27 meet "Requirement A" of the second paragraph of 35 U.S.C. 112.

Further in the communication filed on August 19, 2010 by the Applicant, case law of *Solomon v. Kimberly-Clark Corp.*, *In re Prater* and *In re Cormany* were cited to delineate that evidence showing that a claim does not correspond in scope with that which the applicant regards as the invention may be found in contentions or admissions contained in briefs or remarks filed by the applicant or in affidavits filed under 37 CFR 1.132. For the record, it is Applicant's presumption that the Examiner's statement on page 7 of the Office Action declaring the case law of *Solomon v. Kimberly-Clark Corp.*, *In re Prater* and *In re Cormany* not being relevant to the instant invention pertains to the Examiner's acknowledgement that no remarks have been filed by the Applicant that would render the claimed subject matter as not corresponding in scope with that the Applicant regards as the invention. If such a presumption is incorrect, clarification is requested as to the why the case law is not relevant to the captioned case.

With respect to "Requirement B" of the second paragraph of 35 U.S.C. 112 (i.e., the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant), the Applicant noted in the communication filed

August 19, 2010 that definitions for the phrases "functional equivalent," "structural analog" and "sequence analog" are clearly provided in the specification. In reply, the Examiner refuses to acknowledge that the phrases are defined in the specification because the disclosures in the specification regarding the phrases do not define the metes and bounds of the phrases (Office Action, pg. 8). The Examiner appears to elaborate on what she presumes to be a lack of clarity regarding the phrase "functional equivalent" on page 10, lines 1-7 of the Office Action (which is addressed below), but fails to elaborate in the Office Action what the lack of clarity is regarding the phrases "structural analog" and "sequence analog". Referring back to the 35 U.S.C. § 112, 2nd paragraph rejection of claims 21-27 in the Office Action dated February 19, 2010, which the Examiner references as being maintained for the current Office Action, it appears the only bases for the rejection of the phrases "structural analog" and "sequence analog" is the Examiner's position that the examples of chemical modifications disclosed in the specification are not definitive and the term "such as" used to provide some of such examples is indefinite. Such bases for rejection are traversed as set forth below and as in the communication filed August 19, 2010 by the Applicant.

As acknowledged by the Examiner, the specification describes the phrase 'structural analog' as one or more chemical modifications to the peptide backbone or non-side chain chemical moieties of a proteinaceous molecule. In addition, the specification describes the phrase 'sequence analog' as one or more chemical modifications to the side chain chemical moieties, which is also referred to as a residue of one or more amino acid proteinaceous molecule's sequence. The Applicant contends that one skilled in the art would clearly know the metes and bounds of such phrases by such definitions, specifically that there would be no ambiguity for one skilled in the art as to what would constitute a chemical modification and further there would be no ambiguity to what the peptide backbone, non-side chain chemical moieties or side chain chemical moieties of a proteinaceous molecule refer. As set forth in more detail below, the Applicant further contends the use of the phrase "such as" to provide some examples of chemical modifications regarding the terms "structural analog" and "sequence analog" does not induce ambiguity to the terms and, thus, does not render the claims indefinite.

In the communication filed on August 19, 2010 by the Applicant, the Applicant argued that one skilled in the art would be apprised with a reasonable degree of precision and particularity what the terms "similar," "desired properties," "undesired properties," and "desired chemical reactions" refer to for an enzyme and, therefore, the fact that such terms are not defined in the specification does not render the phrases "functional equivalent," "structural analog," and "sequence analog" indefinite. In reply, the Examiner cites *Orthokinetics, Inc. v, Safety Travel Chairs, Inc.* case law, noting "[t]he test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' " (Office Action, pgs. 9-10). The Applicant agrees such case law is applicable to the captioned rejection and notes its specific citation in the communication filed August 19, 2010. The Applicant further notes that the definiteness of claim language must not, however, be limited to disclosure of the specification, but rather must include interpretation by skilled artisans and teachings of prior art.

> The essential inquiry pertaining to this requirement [i.e., the requirement of definiteness] is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
> (B) The teachings of the prior art; and
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.
>
> *MPEP 2173.02 (See also, In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971))*

As noted in the communication filed August 19, 2010 and which the Examiner failed to address in the current Office Action, it is the Applicant's position that the Examiner is improperly analyzing the description of the terms 'functional equivalent,' 'structural analog,' and 'sequence analog' in the specification in a vacuum and is not taking into consideration how one of skill in the art would interpret such terms based on such disclosure. In particular, the Applicant maintains the position that one skilled in the art would be apprised of the scope of the terms "functional equivalent," "structural analog," and "sequence analog" with a reasonable degree of precision and particularity based on the definitions of such terms provided in the specification. In addition, the Applicant maintains that the teachings of examples in the

specification of what may be encompassed in the scope of the terms "functional equivalent," "structural analog" and "sequence analog" does not introduce ambiguity to those terms nor would one skilled in the art view the examples as such.

To substantiate such a position, the Applicant provided a declaration under 37 C.F.R. § 1.132 by Dr. Melinda E. Wales, Ph.D., a person skilled in the art of biotechnology, in accompaniment with the communication filed August 19, 2010. In the declaration, Dr. Melinda E. Wales declared that one skilled in the art of biotechnology would be apprised of the scope of the terms "functional equivalent," "structural analog," and "sequence analog" for claims 21-27 with a reasonable degree of precision and particularity based on the description of such terms provided in the specification and what is readily known in the art regarding E.C. 3.1.8 enzymes, which all claims of the captioned case, including dependent claims 21-27, are directed. On page 11 of the Office Action, the Examiner finds points 9-13 of Dr. Wales' declaration not persuasive for the same reasons the arguments presented by the Applicant in the communication filed August 19, 2010 are refuted. In making such a rebuttal, there is no indication that the Examiner has given any weight or even consideration to Dr. Wales's statements of facts and beliefs in points 9-13 of how one skilled in the art of biotechnology would interpret the meaning of the terms 'functional equivalent,' 'structural analog,' and 'sequence analog' in view of the disclosures in the specification, particularly the definitions of the terms provided in the specification and the examples which may constitute the terms. In view of such, the Applicant reiterates his position that the Examiner is improperly analyzing the description of the terms 'functional equivalent,' 'structural analog,' and 'sequence analog' in the specification in a vacuum and is not taking into consideration how one of skill in the art would interpret such terms based on such disclosure.

The Examiner notes that point 14 in Dr. Wales' declaration is not argued by the Applicant in the communication filed August 19, 2010, but deems the point to be unpersuasive regarding whether one skilled in the art of biotechnology would be apprised of the scope of the terms "functional equivalent," "structural analog," and "sequence analog" for claims 21-27. In particular, the Examiner states the following to refute the applicability of the statements made in point 14 of Dr. Wales' declaration:

> It is acknowledged that EC 3.1.8 encompasses phosphoric triester hydrolases, including EC 3.1.8.1, aryldialkylphosphates, and EC 3.1.8.2, diisopropylfluorophosphatases. However, claims 21-27 fail to use the term EC 3.1.8. Even if claims 21-27 recited equivalents to EC 3.1.8 enzymes , which the claims do not, EC 3.1.8 enzymes is a large and variable family of enzymes with a large number of variable substrates and the potentiality of being involved in many different cellular processes and diseases. Neither the specification nor the claims define the metes and bound of functional equivalents of EC 3.1.8 enzymes. *(Office Action -- pgs. 11-12)*

The Applicant refutes the Examiner's assertion that claims 21-27 fail to use the term EC 3.1.8 and further do not recite equivalents to EC 3.1.8 enzymes. In particular, the Applicant notes that 37 CFR 1.75(c) clearly states "Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." Each of claims 21-27 are dependent from independent claim 1, specifically through intermediary dependent claims 17 and 19. As acknowledged by the Examiner, independent claim 1 includes a limitation of an enzymatically active esterase classified in an enzyme subclass designated by Enzyme Commission number EC 3.1.8. Since the limitations of intermediary dependent claims 17 and 19 and claims 21-27 further specify the enzymatically active esterase recited in independent claim 1, the limitations of claims 21-27 are directed enzymes of E.C. 3.1.8. Consequently, stating the contrary as a basis to deem point 14 in Dr. Wales' declaration filed August 19, 2010 unpersuasive is unsound.

Furthermore, the Applicant traverses the Examiner's basis that "EC 3.1.8 enzymes is a large and variable family of enzymes with a large number of variable substrates and the potentiality of being involved in many different cellular processes and diseases" renders point 14 in Dr. Wales' declaration file August 19, 2010 unpersuasive. In particular, the context of point 14 in Dr. Wales' declaration filed August 19, 2010 elaborates how one skilled in the art of biotechnology would interpret the terms "functional equivalent," "structural analog," and "sequence analog" in regard to the scope to which claims 21-27 are directed, particularly a specific functional class of enzymes within EC 3.1.8. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

Dr. Wales further delineates in her declaration filed August 19, 2010 that the functional class of enzymes to which claims 21-27 are directed can be easily defined by academic literature over the past 20 years and is further limited by the structural and sequence attributes exemplified in dependent claim 21. In the declaration, Dr. Wales acknowledges that there is sequence divergence represented in EC 3.1.8, but the enzymes of claim 21 (i.e., functional equivalent of a *Agrobacterium radiobacter* P230 organophosphate hydrolase, a *Flavobacterium balustinum* parathion hydrolase, a *Pseudomonas diminuta* phosphotriesterase, a *Flavobacterium sp opd* gene product, or a *Flavobacterium sp.* parathion hydrolase *opd* gene product) exemplify a specific class of EC 3.1.8 of limited sequence divergence. It is noted that claims 22-27 are dependent from claim 21 and, thus, do not cause such limited sequence divergence to vary. As such, the fact that EC 3.1.8 is a large and variable family of enzymes with a large number of variable substrates and that the potentiality of being involved in many different cellular processes and diseases exists for enzymes of EC 3.1.8 (as noted by the Examiner on page 12 of the Office Action), such generalities are not applicable to render the metes and bounds of a far more limited class of E.C. 3.1.8 enzymes to which claims 21-27 are directed indefinite. For at least such reasons and further that the Examiner incorrectly asserts claims 21-27 do not recite equivalents of EC 3.1.8 enzymes, the Applicant contends the bases for which the Examiner relies upon to deem point 14 of the declaration by Dr. Melinda E. Wales filed on August 19, 2010 unpersuasive is deficient.

In the communication filed on August 19, 2010 by the Applicant, the Applicant argued that (i) the fact the examples disclosed in specification regarding the terms "functional equivalent," "structural analog," and "sequence analog" do not encompass every possible consideration for the terms does not render the terms indefinite. In particular, the Applicant asserted that those skilled in the art of biotechnology would readily recognize that the examples provided in the specification are offered to support the definitions set forth for the terms, but in no way serve an exhaustive list of possibilities encompassed by the terms. In addition, the Applicant argued the teachings of examples of what may be encompassed in the scope of those terms does not introduce ambiguity to those terms and, thus, does not render the terms indefinite. The Applicant further argued (ii) the terms and phrases "example," "such as" and "may possess" used in such descriptions of the specification acerbate this assertion as a skilled artisan

in any scientific field recognizes that examples are not definitive, the term "such as" refers to examples, and the use of the term "may" does not constitute a necessity. It is noted that Dr. Melinda E. Wales corroborates such statements in point 13 of her declaration filed August 19, 2010. In reply, the Examiner asserts:

> Applicants arguments (i) and (ii) are contradictory. (i) Argues that the skilled artisan, given a few examples, would understand the metes and bounds of the invention. (ii) Argues that examples are not definitive. It is acknowledged that example are not definitive. *(Office Action, pg. 10)*

The Examiner's conjecture that arguments (i) and (ii) are contradictory is traversed. In particular, it is the Applicant's position that although the examples provided in the specification regarding the scope of the terms "functional equivalent," "structural analog," and "sequence analog" are not themselves definitive, the examples provide enough teaching for one skilled in the art to understand the metes and bounds of the terms. In other words, although the examples themselves are not definitive, they infer enough teaching to render the claims definite. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The Applicant reiterates his assertion that those skilled in the art of biotechnology would readily recognize that the examples provided in the specification are offered to support the definitions set forth for the terms (i.e., the examples support the definiteness of the terms), but in no way serve an exhaustive list of possibilities encompassed by the terms (i.e., the examples themselves are not definite).

As noted above, the Examiner fails to elaborate in the current Office Action what the lack of clarity is regarding the terms "structural analog" and "sequence analog". As also noted above, it appears, based on the 35 U.S.C. § 112, 2nd paragraph rejection of claims 21-27 in the Office Action dated February 19, 2010, which the Examiner references as being maintained for the current Office Action, the only bases for the rejection of the phrases "structural analog" and "sequence analog" is the Examiner's position that the examples of chemical modifications disclosed in the specification are not definitive and the term "such as" used to provide some of

such examples is indefinite. For the reasons set forth above, it is asserted that such bases for rendering the terms "structural analog" and "sequence analog" indefinite is faulty.

As further noted above, the Examiner appears to elaborate on page 10, lines 1-7 of the Office Action as to what she presumes to be a lack of clarity regarding the phrase "functional equivalent". In particular, she states:

> .. for example for the phrase "functional equivalent," it is unclear whether said phrase means a protein that, compared to a specific reference protein (i) has the exact same substrate specificity, (ii) catalyzes the exact same reaction, (iii) has the same Vmax, (iv) has the same Kcat, (v) has the same immunogenicity, (vi) has the same modulators, (vii) has the same binding partners, (viii) is in the same signal transduction pathway(s), (ix) can complement loss of the specific reference protein, (x) mutation of causes the same cellular effect, (xi) has all of (i)-(x), or (xii) has some combination of (i)-(x). *(Office Action – pg. 10)*

In response to such comments, the Applicant contends such specificity is not needed for one skilled in the art to delineate the metes and bounds of the terms "functional equivalent," "structural analog" and "sequence analog". In particular, the Applicant maintains the position that the one skilled in the art of biotechnology would be apprised of the scope of the terms "functional equivalent," "structural analog," and "sequence analog" for claims 21-27 with a reasonable degree of precision and particularity based on the description of such terms provided in the specification (i.e., including the definitions of the terms provided in the specification as well as the examples of chemical modifications and enzymatic activity encompassing such terms) and what is readily known in the art regarding E.C. 3.1.8 enzymes.

Further to the aforementioned arguments, the Applicant notes that, in addition to being rejected under 35 U.S.C. § 112, second paragraph for being indefinite, claims 21-27 are twice rejected under 35 U.S.C. § 103(a) in the current Office Action. In particular, claims 21-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over by U.S. Patent No. 5,998,200 to Bonaventura et al. (hereinafter refered to as "Bonaventura) in view of a paper entitled "*Rational design of organophosphorus hydrolase for altered substrate specificities*," by Di Sioudi et al. and in further in view of a datasheet for enzymes classified as EC 3.1.8.1 taken from the ExPASy (Expert Protein Analysis System) Proteomics Server provided by the Swiss Institute of

Bioinformatics or in view of a paper entitled "*Immobilization of β-Galactosidase for Application in Organic Chemistry Using a Chelating Peptide*" to Piesecki et al.

Given that the Examiner was able to examine the patentability of claims 21-27 relative to the cited references indicates that there is not a great deal of confusion or uncertainty of how one may interpret the phrases "functional equivalent," "structural analog" and "sequence analog" in the claims. As such, the Applicant refutes the Examiner's inference on page 10 of the current Office Action (i.e., the list of 12 clarifications which the Examiner notes the specification and the claims being unclear on for defining the metes and bounds of the term "functional equivalent") that there a great deal of confusion and uncertainty as to the proper interpretation of the term "functional equivalent". In fact, in order to properly examine the claims, the Examiner must have been able to ascertain at least one interpretation of the phrases which presumably rendered the claims unpatentable. The Applicant notes that the Examiner fails to point out in the current Office Action or in the previous Office Action dated February 19, 2010 how the term "functional equivalent" is interpreted for the 35 U.S.C. § 103(a) rejection of claims 21-27.

To support the aforementioned assertions, the Applicant refers to MPEP 2173.06 regarding approaches for examining a purportedly indefinite claim relative to prior art:

> All words in a claim must be considered in judging the patentability of a claim against the prior art. *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970). … When the terms of a claim are considered to be indefinite, at least two approaches to the examination of an indefinite claim relative to the prior art are possible.
>
> First, where the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections: (A) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph; and (B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable. See, e.g., *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). When making a rejection over prior art in these circumstances, it is important for the examiner to point out how the claim is being interpreted. Second, where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a

> claim, it would not be proper to reject such a claim on the basis of prior art. As stated in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), a rejection under 35 U.S.C. 103 should not be based on considerable speculation about the meaning of terms employed in a claim or assumptions that must be made as to the scope of the claims. *(MPEP 2173.06)*

To further substantiate the Applicant's position that one skilled in the art would be apprised of the scope of the terms "functional equivalent," "structural analog," and "sequence analog" with a reasonable degree of precision and particularity based on the definitions and examples of such terms provided in the specification, the Applicant provides numerous prior art references in Exhibit A filed in accompaniment with this communication, which use the terms in the manner described in the specification. The citations of the terms in each of the references and the context to which they are used are set forth below.

In relation to the term 'functional equivalent,' the Applicant refers to U.S. Patent No. 5,726,023 to Cheever et al. (hereinafter referred to as "Cheever"), U.S. Patent No. 5,728,377 to Sarris et al. (hereinafter referred to as "Sarris") and U.S. Patent No. 6,719,902 to Alvarez et al. (hereinafter referred to as "Alvarez"). For example, col. 8, lines 51-58 of Cheever mentions that a functional equivalent is "... where one or more amino acids are replaced by other amino acid(s) or non-amino acid(s) which do not substantially affect function". In addition, both Sarris (*see*, e.g., col. 11, lines 1-57) and Alvarez (*see*, e.g., col. 22, line 60 to col. 24, line 41) discuss the term "functional equivalent" in relation to how certain amino acids may be substituted for other amino acids in a protein structure without appreciable loss of biological activity. It is asserted that the cited passages show that the term "functional equivalent" was a well known term in the art prior to the priority date of the captioned application, specifically referring to a proteinaceous molecule in which one or more amino acids have been substituted relative to a native protein and further which functions in a manner similar to the native protein. It is noted that the use of the term "functional equivalent" in Cheever, Sarris and Alvarez is in scope with the definition of the term provided in the specification of the captioned case. In particular, the term used in each of the references reads on a proteinaceous molecule comprising a sequence analog of an enzyme (the scope of the term "sequence analog" in the specification includes amino acid substitutions –

see, e.g., ¶ 0169) and further wherein the proteinacious molecule functions in a manner similar to the enzyme.

Regarding the term "structural analog," the Applicant refers to U.S. Patent No. 7,105,488 to Tarasova et al. (hereinafter referred to as "Tarasova"). In particular, column 3, lines 45-56 of Tarasova describes an embodiment of an invention directed to an isolated G protein-coupled receptor (GPCR)-modulating molecule comprising a peptide or peptidomimetic that is a structural analog of a portion of a transmembrane domain of a GPCR. Furthermore, column 35, lines 15-26 and column 36, lines 42-50 of Tarasova discuss backbone, terminal and side chain modifications to GPCR peptides to form the inventive GPCR molecules. The cited passages in Tarasova show that the term "structural analog" was a well known term in the art prior to the priority date of the captioned application, specifically referring to a proteinaceous molecule in which side chain residues, terminal residues and/or its peptide backbone have been modified and/or which chemical moieties have been added relative to a native molecule particularly for modulating biological properties or activity of the native molecule. It is further noted that the use of the term "structural analog" in Tarasova is in scope with the definition of the term provided in the specification of the captioned case, specifically that a structural analog refers to one or more chemical modifications to the peptide backbone or non-side chain chemical moieties of a proteinaceous molecule.

In addition to the citation of Tarasova, the Applicant refers to *Structural studies of "active complex" of bleomycin: Assignment of ligands to the ferrous ion in a ferrous-bleomycni-carbon monoxide complex* to Oppenheimer et al. (hereinafter referred to as "Oppenheimer") for the term "structural analog". In particular, the Abstract of Oppenheimer states the addition of carbon monoxide to Fe(II)-bleomycin forms a putative structural analog of Fe(II)-bleomycin-O_2 complex. As one skilled in the art would recognize, the diatomic oxygen and carbon monoxide components of the complexes are non-side chain chemical moieties and, more specifically, prosthetic groups. Thus, the teaching in Oppenheimer of Fe(II)-bleomycin-CO complex being a putative structural analog of Fe(II)-bleomycin-O_2 complex not only shows that the term was well known in the art prior to the priority date of the captioned application, but is in scope with the definition of the term provided in the specification of the captioned case. Specific reference is

made to paragraph [0169] of the specification, which states the context of a structural analog includes modification to a prosthetic group.

> In certain aspects, a subcomponent of an enzyme such as an apo-enzyme, a prosthetic group, a co-factor, or a combination thereof, may be modified to produce a functional equivalent structural analog. In particular facets, such an enzyme sub-component that does not comprise a proteinaceous molecule may be altered to produce a functional equivalent structural analog of an enzyme when combined with the other sub-components. (*Specification -- ¶ 0169*)

In relation to the term "sequence analog," the Applicant refers to U.S. Patent No. 6,110747 to Blaschuk et al. (hereinafter referred to as "Blaschuk"). In particular, column 7, lines 59-62 refers to a sequence "or an analogue thereof" and column 8, line 61 uses the specific term "sequence analogue". Column 8, lines 34-60 discusses what this term means. In particular, lines 39-41 of column 8 state that "An analogue may contain any of a variety of amino acid substitutions, additions, deletions and/or modifications". The cited passages show that the term "sequence analog" was a well known term in the art prior to the priority date of the captioned application, specifically referring to a peptide sequence which has at least 50% sequence identity to its native sequence and may include any variety of amino acid substitutions, addition, deletions, and/or modifications. It is further noted that the use of the term "sequence analog" in Blaschuk is in scope with the definition of the term provided in the specification of the captioned case, specifically that a sequence analog refers to one or more chemical modifications to side chain chemical moieties of a proteinaceous molecule, which can include amino acid substitutions, addition, deletions, and/or modifications as set forth in paragraphs [0119] and [0169] of the specification and original claims 25, 32, 38, 57 and 59.

It is noted that although the terms in question and used in Cheever, Sarris, Alvarez, Tarasova, Oppenheimer and Blaschuk may be broader and/or narrower in scope relative to the definitions provided in the specification for such terms, such a variation does not render the terms indefinite. Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d

1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) (underline added for emphasis). As set forth above and in the communication filed August 19, 2010 by the Applicant and further in the declaration by Dr. Melinda E. Wales filed August 19, 2010, the terms "functional equivalent," "structural analog" and "sequence analog" are clearly defined in the specification. In addition, the specification describes the terms in a manner that the one skilled in the art of biotechnology would be apprised of the scope of the terms with a reasonable degree of precision and particularity. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more. *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986).

Lastly, on page 10 of the Office Action, the Examiner states that she cannot find any specific examples in the specification of proteins that are "functional equivalents," "structural analogs" or "sequence analogs". The Applicant respectfully disagrees. Exemplary citations of specific examples of sequence analogs are disclosed in ¶0036 and ¶0040, listing various amino acid substitutions which may make up sequence analogs of *Pseudomonas diminuta* phosphotriesterase and *Loligo vulgaris* DFPase:

> In particular facets, the *Pseudomonas diminuta* phosphotriesterase functional equivalent comprises a sequence analog. In some facets, the sequence analog comprises an amino acid substitution. In specific facets, the sequence analog comprises H55C, H57C, C59A, G60A, S61A, I106A, I106G, W131A, W131F, W131K, F132A, F132H, F132Y, L136Y, L140Y, H201C, H230C, H254A, H254R, H254S, H257A, H257L, H257Y, L271A, L271Y, L303A, F306A, F306E, F306H, F306K, F306Y, S308A, S308G, Y309A, M317A, M317H, M317K, M317R, H55C/H57C, H55C/H201C, H55C/H230C, H57C/H201C, H57C/H230C, A80V/S365P, I106A/F132A, I106A/S308A, I106G/F132G, I106G/S308G, F132Y/F306H, F132H/F306H, F132H/F306Y, F132Y/F306Y, F132A/S308A, F132G/S308G, L182S/V310A, H201C/H230C, H254R/H257L, H55C/H57C/H201C, H55C/H57C/H230C, H55C/H201C/H230C, I106A/F132A/H257Y, I106A/F132A/H257W, I106G/F132G/S308G, L130M/H257Y/I274N, H257Y/I274N/S365P, H55C/H57C/H201C/H230C, I106G/F132G/H257Y/S308G, A14T/A80V/L185R/H257Y/I274N, or a combination thereof. (*Specification -- ¶ 0036*)

In particular facets, the *Loligo vulgaris* DFPase functional equivalent comprises a sequence analog. In continuing facets, the sequence analog comprises an amino acid substitution. In some facets, the sequence analog is H181N, H224N, H274N, H219N, H248N, or H287N. (*Specification -- ¶ 0040*)

In addition, structural analogs of OPH enzymes are disclosed in ¶0169:

OPH normally binds two atoms of Zn^{2+} per monomer when endogenously expressed. While binding Zn^{2+}, this enzyme is one of the most stable dimeric enzymes known, with a thermal temperature of melting ("T_m") of approximately 75°C and a conformational stability of approximately 40 killocalorie per mole ("kcal/mol") (Grimsley, J. K. et al., 1997). However, structural analogs have been made wherein Co^{2+}, Fe^{2+}, Cu^{2+}, Mn^{2+}, Cd^{2+}, or Ni^{2+} are bound instead to produce enzymes with altered stability and rates of activity (Omburo, G. A. et al., 1992). For example, Co^{2+} substituted OPH does possess a reduced conformational stability (~22 kcal/mol). But this reduction in thermal stability is offset by the superior catalytic activity of Co^{2+} substituted OPH in degrading various OP compounds. For example, five-fold or greater rates of detoxification of sarin, soman, and VX were measured for Co^{2+} substituted OPH relative to OPH binding Zn^{2+} (Kolakoski, J. E. et al., 1997). It is contemplated that structural analogs of an OPH sequence may be prepared comprising a Zn^{2+}, Co^{2+}, Fe^{2+}, Cu^{2+}, Mn^{2+}, Cd^{2+}, Ni^{2+}, or a combination thereof. Generally, changes in the bound metal can be achieved by using cell growth media during cell expression of the enzyme wherein the concentration of a metal present is defined, and/or removing the bound metal with a chelator (*e.g.*, 1,10-phenanthroline; 8-hydroxyquinoline-5-sulfphonic acid; ethylenediaminetetraacetic acid) to produce an apo-enzyme, followed by reconstitution of a catalytically active enzyme by contact with a selected metal (Omburo, G. A. et al., 1992; Watkins, L. M. et al., 1997a; Watkins, L. M. et al., 1997b). It is further contemplated that structural analogs of an OPH sequence may be prepared to comprise only one metal atom per monomer. *(Specification --¶0036)*

For at least the reasons set forth above, it is asserted that one skilled in the art would be apprised with a reasonable degree of precision and particularity what the terms "functional equivalent," "structural analog," and "sequence analog" refer to and, thus, the phrases "functional equivalent," "structural analog" and "sequence analog" are definite in claims 21-27. Accordingly, removal of all the § 112, 2nd paragraph rejection is respectfully requested.

Section 112, 1st Paragraph, Enablement Rejection

Claims 1, 15-27, 67, 72-75, 79-89, 94-100, 102, 110-112, 115-117, 123-135, 180-182, 217, 219-242, 251-255, 272, 323, 324, 326, 327, 343-356, 360-362, 365-373, 376, 377, 379-385, 389-391, 393 and 394 were rejected under 35 U.S.C. § 112, first paragraph for the specification failing to provide enablement for the subject matter of the claims. The Applicant respectfully traverses the rejection of the pending claims and maintains the arguments presented in the communications filed August 27, 2008, September 28, 2009 and August 19, 2010 by the Applicant. The arguments are incorporated by reference as if fully set forth herein, but all have not been reiterated below for the sake of brevity. The Examiner responds to some of the arguments in the current Office Action in support of her position to maintain the rejection. Such responses are paraphrased below along with rebuttals by the Applicant.

In the communication filed on August 19, 2010 by the Applicant, the Applicant cites several paragraphs of the specification that clearly and amply describe the manner of making coatings, elastomers, adhesives, sealants, and waxes with active enzymes and further with known components for imparting desired properties for coatings, elastomers, adhesives, sealants, and waxes. In response, the Examiner acknowledges the cited paragraphs describe a variety of coatings, elastomers, adhesives, sealants and waxes as well as components thereof and manufacturers thereof (Office Action, pg. 13). Further in the communication filed on August 19, 2010, the Applicant cites several paragraphs of the specification that clearly set forth that an enzyme formulated within such coatings, elastomers, adhesives, sealants, and waxes may be any active enzyme of E.C. 3.1.8. In response, the Examiner acknowledges some of the cited paragraphs, specifically ¶¶ 0134-0152, 0181-0191, 0202 and 0205, describe enzymes of E.C. 3.1.8 (Office Action, pg. 13).

Upon reviewing the latter statement, it appears that there may be a discrepancy in the documents in which the Applicant and the Examiner is referring to for citations. In particular, the Applicant has been referring to the replacement specification filed January 28, 2004 for citations of support in the captioned case, while it appears the Examiner is referring to Patent Application Publication No. 2004/0109853. As an example, the section in the application under the heading "Preferred Enzymes" is noted in ¶¶ 0129-0153 in the replacement specification filed January 28,

2004 and the same section is reflected in ¶¶ 0134-0165 in Patent Application Publication No. 2004/0109853. To clarify discussions regarding support and to avoid future confusion, the Applicant requests the Examiner make known which document she wishes to have cited for support in the future. Until then, the Applicant will continue to cite the replacement specification filed January 28, 2004.

Although the Examiner acknowledges that the specification describes a variety of surface treatments and discusses enzymes of E.C. 3.1.8, the Examiner contends:

> … none of said paragraphs teach the skilled artisan how to make and use a paint comprising an active enzyme of E.C. 3.1.8. Mere disclosure of (i) a laundry list of coatings, elastomers, adhesives, sealants, and waxes as well as components thereof and manufactures thereof and (ii) a laundry list of enzymes of E.C. 3.1.8 does not enable the skilled artisan to make an[d] use any paint comprising any enzyme of E.C. 3.1.8, wherein the enzyme has any structure and any E.C. 3.1.8 esterase activity. *(Office Action, pg. 13)*

The Applicant respectfully disagrees. The paragraphs cited by the Applicant in previous communications do not provide a mere laundry list of information regarding enzymes of E.C. 3.1.8 and coatings, elastomers, adhesives, sealants, and waxes in which they can be incorporated. Rather, as the Applicant has previously contended and is further set forth below, the cited paragraphs provide clear teaching of how to make and use coatings, elastomers, adhesives, sealants, and waxes with active enzymes of E.C. 3.1.8.

Although the information provided in the cited paragraphs is vast and has a broad scope, it is improper to construe such breadth as being simply a listing of possibilities from which the claimed subject matter can be derived. Moreover, in view of the breadth of the pending claims, specifically that they apply to various surface treatments having any active enzyme of E.C. 3.1.8 or functional equivalent thereof, the Applicant contends that in order to enable such breadth, a vast disclosure is needed to insure one skilled in the art would know how to make and use the claimed subject matter. In particular, the specification of the captioned case specifically guides those skilled in the art how to select and prepare an enzyme for incorporation within a surface treatment composition, how to make the surface treatment composition with the selected enzyme, and further how to test and use the resulting composition. In such a manner, one skilled in the art can make and use a surface treatment

composition with an active enzyme, particularly in reference to the pending claimed subject matter of coatings, elastomers, adhesives, sealants, and waxes with any active enzyme of E.C. 3.1.8.

To substantiate the Applicant's position, several select paragraphs of the specification are highlighted (i.e., quoted and/or paraphrased) below which enable one skilled in the art to make and use coatings, elastomers, adhesives, sealants, and waxes with active enzymes of E.C. 3.1.8. It is noted that such citations do not include every disclosure in the specification which may contribute to enablement of the currently claimed subject matter. Rather, the citations below are provided to show that the specification includes specific teachings for enabling the currently claimed subject matter of the case versus providing a mere laundry list of information regarding enzymes of E.C. 3.1.8 and a laundry list of various coatings, elastomers, adhesives, sealants, and waxes in which they can be incorporated as purported by the Examiner. It is further noted that assuming the request noted above to reinstate claims 319-321 will be granted, some of the claims of the case will be directed to elastomers, adhesives, sealants, and waxes and, thus, enablement for such compositions are provided below.

Citations of enablement for selecting and preparing an active enzyme of E.C. 3.1.8

> As used herein, a "biomolecule" refers to a compound comprising of one or more chemical moieties typically synthesized in living organisms, including but not limited to, an amino acid, a nucleotide, a polysaccharide or simple sugar, a lipid, or a combination thereof. A preferred biomolecule of the present invention comprises a proteinaceous molecule. As used herein a "proteinaceous molecule" comprises a polymer formed from amino acids, such as a peptide or a polypeptide. Examples of proteinaceous molecules include an enzyme ... (*Specification -- ¶ 0113*)
>
> After production of a biomolecule by a living cell, the composition comprising the biomolecule may undergo one or more processing steps to prepare a biomolecule composition of the present invention. Examples of such steps include permeabilizing, disrupting, sterilizing, concentrating, drying, resuspending, or a combination thereof. (*Specification -- ¶ 0241*)
>
> The selection of a biomolecule for use in the present invention depends on the desired property that is to be conferred to a composition of the present invention. A preferred biomolecule of the present invention comprises an enzyme, as enzymatic activity is a preferred property to be conferred to a biomolecule composition, coating and/or paint in the present invention. As used herein, the term "enzyme" refers to a molecule that possesses the ability to accelerate a chemical reaction, and comprises

one or more chemical moieties typically synthesized in living organisms, including but not limited to, an amino acid, a nucleotide, a polysaccharide or simple sugar, a lipid, or a combination thereof. (*Specification -- ¶ 0116*)

In preferred embodiments, an enzyme comprises a proteinaceous molecule. It is contemplated that any proteinaceous molecule that functions as an enzyme, whether identical to the wild-type amino acid sequence encoded by an isolated gene, a functional equivalent of such a sequence, or a combination thereof, may be used in the present invention. (*Specification -- ¶ 0117*)

A preferred enzyme for use in the present invention comprises a hydrolase. A preferred hydrolase comprises an esterase. A preferred esterase comprises an esterase that catalyzes the hydrolysis of an organophosphorus compound. Examples of such preferred esterases are those identified by enzyme commission number EC 3.1.8, the phosphoric triester hydrolases. As used herein, a phosphoric triester hydrolase catalyzes the hydrolytic cleavage of an ester from a phosphorus moiety. Examples of a phosphoric triester hydrolase include an aryldialkylphosphatase, a diisopropyl-fluorophosphatase, or a combination thereof. (*Specification -- ¶ 0129*)

It is contemplated that any phosphoric triester hydrolase that is known in the art may be used in preferred embodiments of the present invention. (*Specification -- ¶ 0153*)

Citations of enablement for making coating compositions with active enzymes of E.C. 3.1.8

It is contemplated that any described coating composition may be altered (*e.g.*, by direct addition and/or coating component substitution) to incorporate the biomolecular composition of the present invention. The previous embodiments of the invention primarily described compositions and techniques for preparing, testing, and using a coating prepared *de novo*. However, it is contemplated that the biomolecular composition of the present invention may be incorporated into a standard coating by direct addition, as described in Example 3. (*Specification -- ¶ 0705*)

Examples of a coating of the present invention include a clear coating or a paint. (*Specification -- ¶ 0264*)
(Note: various types of coatings and coating components as well as considerations for making coatings with active biomolecules, particularly enzymes are described in ¶¶0266-0621.)

In an example of use of the powder prepared as described in Example 2, 3 mg of the milled powder was added to 3 ml of 50% glycerol. The suspension was then added to 100 ml of Olympic® premium interior flat latex paint (Olympic®, One PPG Place, Pittsburg, PA 15272 USA). This paint with biomolecular composition was then used

to demonstrate the activity of the paint biomolecular composition in hydrolysis of a pesticide or a nerve agent analog. (*Specification -- ¶ 0678*)

(Note: this citation is under the headings of Example 3 and Two-Pack OPH Paint Coating: OPH Powder and Latex Paint in the specification.)

Citations of enablement for testing coating compositions with active enzymes of E.C. 3.1.8

The ability of a biomolecule to retain its function as an active biomolecule in a composition of the present invention, particularly a coating, may be detected and measured by any technique known to one of ordinary skill the art, including the various assays described herein. (*Specification -- ¶ 0028*)

General procedures for empirically determining the purity/properties of various coating components and/or coating compositions are known to those of ordinary skill in the art, and may be applied in the practice of the present invention. Such procedures include measurement of density, volume solids and/or specific gravity, of a coating component and/or coating composition, for purposes such as verification of component identity, aid in coating formulation, maintaining coating batch to batch consistency, *etc.* (*Specification -- ¶ 0647*)

Citations of enablement for using coating compositions with active enzymes of E.C. 3.1.8

A coating may be applied to a surface using any technique known in the art. A in the context of a coating, "application," "apply," or "applying" is the process of transferring of a coating to a surface to produce a layer of coating upon the surface. As known herein, an "applicator" is a devise that is used to apply the coating to a surface. Examples of an applicator include a brush, a roller, a pad, a rag, a spray applicator, *etc.* Application techniques that are contemplated as suitable for a user of the present invention of little or no particular skill include, for example, dipping, pouring, siphoning, brushing, rolling, padding, ragging, spraying, *etc.* Certain types of coatings may be applied using techniques contemplated as more suitable for a skilled artisan such as anodizing, electroplating, and/or laminating of a polymer film onto a surface. (*Specification -- ¶ 0269*)

The invention provides a method of detoxification of a surface contaminated with an organophosphorus compound, comprising the step of: contacting a surface contaminated with an organophosphorous compound with a coating comprising a biomolecule composition, wherein the biomolecule composition comprises a phosphoric triester hydrolase. (*Specification -- ¶ 0082*)

The invention provides a method of detoxification of an organophosphorus compound, comprising the step of: contacting an organophosphorous compound with a coating comprising a biomolecule composition, wherein the biomolecule composition comprises a phosphoric triester hydrolase. (*Specification -- ¶ 0083*)

> The invention provides methods of reducing the concentration of an organophosphorus compound upon a surface, comprising the steps of: applying to the surface a coating comprising a biomolecule composition, wherein the biomolecule composition comprises a phosphoric triester hydrolase, and contacting the surface with an organophosphorus compound. (*Specification -- ¶ 0084*)

Citations of enablement for making and using elastomers with active enzymes of E.C. 3.1.8

> It is contemplated that a biomolecular composition may also be incorporated into an elastomer. Elastomers ("rubbers") are polymers that can undergo large, but reversible, deformations upon a relatively low physical stress. It is contemplated that an elastomer composition may incorporate a biomolecular composition of the present invention, such as by preparation with the biomolecular composition and/or direct addition such as by a multi-pack composition. (*Specification -- ¶ 0712*)

See also citations of enablement for making coating compositions with active enzymes of E.C. 3.1.8. It is asserted that one of ordinary skill in the art would be readily able to adapt these teachings to other materials e.g., elastomers.

Citations of enablement for making and using adhesives and sealants with active enzymes of E.C. 3.1.8

> A sealant is a composition capable of attaching to at least two surfaces, filling the space between them to provide a barrier or protective coating. In certain embodiments, a biomolecular composition may be used as a component of an adhesive or a sealant, such as, for example, by direct addition, substitution of an adhesive or sealant component (*e.g.*, a particulate material), or a combination thereof. (*Specification -- ¶ 0714*)

See also citations of enablement for making coating compositions with active enzymes of E.C. 3.1.8. It is asserted that one of ordinary skill in the art would be readily able to adapt these teachings to other materials e.g., adhesives and sealants.

Citations of enablement for making and using waxes with active enzymes of E.C. 3.1.8

> It is contemplated that a biomolecular composition may also be incorporated into a material applied to a surface after manufacture, such as, for example, a wax. (*Specification -- ¶ 0717*)

See also citations of enablement for making coating compositions with active enzymes of E.C. 3.1.8. It is asserted that one of ordinary skill in the art would be readily able to adapt these teachings to other materials e.g., waxes.

Further in the communications filed on August 27, 2008, September 28, 2009 and August 19, 2010 by the Applicant, the Applicant asserted that those of skill in the art of biotechnology are

aware and readily recognize that an active enzyme of E.C. 3.1.8 may be derived by techniques which are known in the art. Moreover, the Applicant asserted that one skilled in the art of biotechnology would be apprised, based on their knowledge of enzymes and the teachings in the specification, of how to analyze and test the enzymatic activity of coatings, elastomers, adhesives, sealants, and waxes formulated with enzymes. Thus, the Applicant asserted that one skilled in the art would be apprised of how to identify a structure of an enzyme of EC 3.1.8, or variants or analogs thereof, which are active within a coating, elastomer, adhesive, sealant, or wax. Furthermore, the Applicant asserted one skilled in the art would be able to establish a rational and predictable scheme for identifying or making a genus of EC 3.1.8 enzymes having activity within a coating, elastomer, adhesive, sealant, or wax. As such, although the number of enzymes to screen for applicable activity in a coating, elastomer, adhesive, sealant, or wax may be vast, the number is not unlimited as purported by the Examiner and screening such a number does not cause undue experimentation.

In reply to such arguments, the Examiner acknowledges on page 14 of the current Office Action that a considerable amount of experimentation is permissible if it is routine or if the specification provides a reasonable amount of guidance for the direction of the experimentation. The Examiner maintains, however, that in the instant case, the making and testing of all paints having any enzyme of E.C. 3.1.8 represents undue experimentation (Office Action, pg. 14). The Examiner cites *Protein tolerance to random amino acid change* to Guo et al. (hereinafter referred to as "Guo") to support her position (i.e., the Examiner references Guo in Reply (H) on pages 14-15 of the Office Action mailed February 19, 2010). Guo is also referenced on page 16 of the current Office Action in response to points 21 and 23 made in a declaration under 37 C.F.R. § 1.132 by Dr. Melinda E. Wales, Ph.D., a person skilled in the art of biotechnology, which was filed in accompaniment with the communication filed August 19, 2010 by the Applicant.

The Examiner purports on page 16 of the Office Action that Guo teaches 34% of some proteins are inactivated by random single-substitution mutations and that the percentage of active mutants for multiple mutations appears to be exponentially related to this by a "simple formula" of $(0.66)^X$ x 100%, where X is the number of mutations introduced. The Examiner applies this estimate to a 325 amino acid phosphotriesterase at 80% identity and 70% identity and computes that the respective quantities of obtainable active mutants is quite low (i.e., 1.8×10^{-10} % at 80% identity and

2.1 x 10^{-16} % at 70% identity). Based on such, the Examiner states that finding only a few active mutants within several billion or more mutants would not be possible or at least would take a very long time to accomplish and, thus, would involve undo experimentation. As set forth in more detail below, the Applicant respectfully disagrees with the Examiner's limited application of Guo's teachings to support the supposition that screening for enzymes which maintain their function in paints would cause undue experimentation for those skilled in the art. In addition, the Applicant notes that the Examiner has failed to acknowledge several teachings in Guo which contradict such a supposition, particularly that the probability of finding proteins which tolerate amino acid changes is actually much higher in most libraries than just a "few out of several billion" as the Examiner purports for Guo.

Although it is feasible to limit a library of mutants of a 325 amino acid phosphotriesterase at 80% identity or 70% identity, it would not be prudent or logical to do so for screening for mutations for the claimed subject matter, particularly based on the teachings of the specification and what is known and commonly done by those skilled in the art. First, the claimed subject matter is not limited to mutants of a particular identity percentage and, thus, there is no reason why one skilled in the art would limit a screening to a particular identity percentage in view of the pending claims. Furthermore, it appears the Examiner has erroneously merged the concepts of mutant variants (which Guo is directed to) with natural variants. As those skilled in the art are aware, it is not uncommon for natural variants to have 70-80% identity, but in such cases nature has eliminated the inactive variants through selection and, thus, finding an active protein among natural variants is a relatively easy task. Mutagenesis is generally limited to a much higher identity percentages. The Applicant notes that the teachings of Guo is in accord with such an assertion in that the number of amino acid changes evaluated for mutants of human 3-methyladenine DNA glycosylase (hereinafter referred to as "AGG") was between 1 and 11 (*see*, Table 1) and the average mutation frequency was 2.2, 4.6 and 6.2 (*see*, Abstract; Table 1; and pg. 9206, 1st col., 3rd full ¶, lines 1-3). Furthermore, many of the examples and discussions in the specification regarding amino acid changes suggest (but do not necessarily limit) libraries having five or less amino acid changes may be effective for finding active mutants (*see*, e.g., ¶¶ 0036, 0156, 0165 and 0172).

Moreover, it is well known to those skilled in the art that the effects of mutations on protein function are additive. It is noted that such an assertion is well supported in Guo (e.g., in the footnote in of Table 1, "As expected, increasing average mutation load results in lower percentage of active enzymes"; by Equation 1; and pg. 9207, 1st col., 2nd full ¶, lines 5-6). In addition, it is well known to skilled artisans that mutations are usually conducted in series, starting with a single mutation. Given such common knowledge, it would not be conducive for one skilled in the art to start with and/or limit a screening to proteins having a relatively large number of amino acid changes, such as the 65 and 98 amino acid changes suggested by the Examiner. Rather, the Applicant asserts that one skilled in the art would most likely pursue a library having at least proteins with much fewer amino acid changes, which is not to say that one skilled in the art would not screen proteins having 70% and 80% identities, but they certainly would not limit a screening to such identities particularly when first trying to find mutants which retain their function for the surface treatment compositions of the currently claimed subject matter.

With regard to screening proteins having a limited number of amino acid changes (such as between 1 and 11 as taught in Guo), Guo teaches the proportion of AAG mutants that survive random amino acid changes is relatively high, specifically between 10.7% to 32.7% (*see*, Table 1, % Survival column). Given that Guo teaches the probability of proteins being inactivated by random amino acid changes is relatively consistent among proteins, one skilled in the art would expect survival rates similar to those disclosed in Guo for other proteins. Such an assertion is further substantiated in Guo in reference to teachings of other publications. For example, Guo states "… numerous evolutionary and mutagenesis studies have lead to the assertion that proteins are highly plastic in tolerating amino acid changes (4, 5)." (Guo -- pg. 9205, 1st col., 2nd full ¶, lines 13-15). In addition, Guo states, "… the isolation of active mutants harboring <u>many</u> mutations from large random mutagenesis libraries ($>10^5$) is not surprising (25)." (Guo -- pg. 9209, 2nd col., 1st full ¶, lines 9-11; underline added for emphasis). As such, if one skilled in the art were to screen a protein (such as a 325 amino acid phosphotriesterase) in the manner noted above by the Applicant and in accordance with expected practice (e.g., screening a library which includes mutants having around 10 or less amino acid changes), then finding tolerable mutants would neither be difficult nor take an enormous amount of experimentation and time as in comparison to the example the Examiner used in the Office Action. Consequently, the Applicant refutes the Examiner's application of Guo's

teachings to substantiate that there would be undue experimentation for one skilled in the art to identify a structure of an enzyme of EC 3.1.8, or variants or analogs thereof, to be active within a coating, elastomer, adhesive, sealant, or wax.

Furthermore, it is noted that Guo's teaching of 34% inactivation of AAG refers to single amino acid changes occurring randomly in a protein (Guo -- pg. 9206, 2nd col., lines 8-10). However, Guo further teaches that some regions of proteins may be more tolerant of mutations than others and those skilled in the art may be apt to concentrate on such regions when trying to find tolerant mutations (*see*, e.g., Guo -- pg. 9208, 2nd col., line 5 to pg. 9209, 2nd col., line 9 and pg. 9210, the ¶ extending between the 1st and 2nd columns). In addition, the specification of the captioned case clearly teaches that some amino acid changes may improve enzyme function and such amino acid changes can be identified by numerous manners (*see*, e.g., Specification -- ¶¶ 0159-0163). As such, if one skilled in the art chooses to screen a library of proteins having amino acid changes which have been identified to be more tolerable and/or improve protein function, then even higher probabilities of proteins which retain their functionality should be obtained (i.e., relative to what is taught in Table 1 for amino acids which are randomly changed in Guo). Since the identification of such amino acid changes are well known in the art, the Applicant asserts that such a process would neither be undue nor contribute to undue experimentation for screening of proteins. Furthermore, the Applicant asserts that screening assays for enzyme activity is also known to those in the art and described in the specification and such process are not undue for a skilled artisan either.

Guo further teaches that even if amino acids which are known to be less tolerable to substitutions in proteins are substituted in a protein, the probability of the protein sustaining its functionality with such substitutions is still relatively high (*see*, the probabilities of tolerant mutations ranging from 2 % to 32 % in the Survival Fraction column in Table 2 of Guo for proteins having concentrations of mutations near enzyme active sites). As such, even if one skilled in the art chooses to screen a library of proteins having amino acid changes which have been identified to be susceptible to inactivation, the number of active mutants obtained would still be ample. Thus, finding tolerable mutants would neither be difficult nor take an enormous amount of

experimentation and time and, thus, there would not be undue experimentation for one skilled in the art to do so.

Lastly in regard to the Examiner's comments in view of Guo, it is noted that the "simple formula" of $(0.66)^X$ x 100% relied upon by the Examiner is incorrect. In particular, the Examiner erroneously used the value of 0.66 as the base of the exponential expression. As shown in Equation 1 of Guo, the base of the exponential expression is 1- X_T. Guo refers to the x-factor of 34% as X_{sub}, which is equal to X_T-*i* (*see*, Equation 2 and the preceding paragraph in Guo). Based on the data of Table 1, which is what X_{sub} is based upon, the average value of *i* is 7.2%, which makes X_T 41.2%. Putting such a value into Equation 1 of Guo results in an exponential expression of $(0.588)^x$ rather than $(0.66)^x$ as purported by the Examiner. Although such a clarification does not affect the Applicant's arguments set forth above regarding undue experimentation, the clarification does affect the active mutant estimates computed by the Examiner for the screening she propose, particularly by three orders of magnitude each.

On page 17 of the Office Action, the Examiner states that independent claims 1, 272, 368, 393 and 394 fail to identify any specific compound as the functional target. The Applicant agrees, but notes that dependent claims 361, 362, 372 and 373 include such specificity, particularly that the enzymatically active esterase is capable of catalyzing one or more chemical warfare agents and one or pesticides, respectively.

In accompaniment with the communication filed on August 19, 2010 by the Applicant, the Applicant provided declarations under 37 C.F.R. § 1.132 by Dr. Melinda E. Wales, Ph.D., a person skilled in the art of biotechnology, and by Dr. James W. Rawlins, a person of skill in the art of coatings and polymer science. In the declarations, Dr. Melinda E. Wales and Dr. James W. Rawlins each declare the specification clearly and sufficiently describes the manner of making and using coatings, elastomers, adhesives, sealants, and waxes including any active enzyme of E.C. 3.1.8. In addition, Dr. Melinda E. Wales declares one skilled in the art of biotechnology would be able to ascertain the possible modifications and tolerances of modification to EC 3.1.8 enzymes to render them active in a coating based on the disclosure in the specification. Moreover, Dr. James W. Rawlins declares one skilled in the art of coatings and polymer science would be able to ascertain

the which coatings and modifications of coating components would inhibit and also have an affect on EC 3.1.8 enzyme activity based on what is readily known in the art and the disclosure in the specification.

On page 15 of the Office Action, the Examiner finds points 20, 22, 24 and 25 of Dr. Wales' declaration not persuasive for the same reasons the arguments presented by the Applicant in the communication filed August 19, 2010 are refuted. On page 17 of the Office Aciton, the Examiner finds points 12-14 of Dr. Rawlins' declaration not persuasive for the same reasons. In making such a rebuttal, there is no indication that the Examiner has given any weight or even consideration to Dr. Wales' and/or Dr. Rawlins' statements of facts and beliefs of how one skilled in their respective arts would interpret the teachings in the specification and apply them in practice to achieve a coating, elastomer, adhesive, sealant, or wax having an enzymatically active enzyme of E.C. 3.1.8. In view of such, the Applicant reiterates his position that there is ample teaching and support in the specification for those skilled in the art to make and use the surface treatment compositions recited in the pending claims.

The Examiner notes that point 15 in Dr. Rawlins' declaration is not argued by the Applicant in the communication filed August 19, 2010, but deems the point that he has made a wide variety of coating compositions with an E.C. 3.1.8 enzyme incorporated therein based on information disclosed in the specification of the captioned case to be unpersuasive. In particular, the Examiner states that since Dr. Rawlins provides no details or evidence as to the coatings made, components thereof, or enzymes used, the Office cannot evaluate or consider such evidence. (Office Action -- pg. 17). The Applicant respectively challenges the Examiner's position that Dr. Rawlins' statements in point 15 cannot be evaluated or considered. In particular, there is no requirement that a person's statements in a declaration under 37 C.F.R. § 1.132 have a particular degree of specificity or that they provide proof to their statements Furthermore, the Applicant asserts that Dr. Rawlins' statements in point 15 are commensurate with the issue at argument, particularly that there is ample teaching, guidance and direction in the specification for one skilled in the art to make a various coatings (including various paints), elastomers, adhesives, sealants, or waxes with any enzymatically active esterase classified as an E.C. 3.1.8 enzyme. The specificity to what enzymes and specific compositions may be used and

specifically in regard to the structure of the enzymes and the components of the compositions is broad, but is not out of the realm for one skilled in the art to determine based on the ample disclosure in the specification as well as what is readily known in the art as set forth in detail above and in each of the communications filed August 27, 2008, September 28, 2009 and August 19, 2010 by the Applicant.

As set forth repeatedly above and in prior communications, it is asserted that the specification enables one skilled in the art to make and use the limitations of the present claims. Accordingly, removal of 35 U.S.C. § 112, first paragraph, enablement rejection of the claims is respectfully requested.

Section 112, 1st Paragraph, Written Description Rejection

Claims 1, 15-27, 67, 72-75, 79-89, 94-100, 102, 110-112, 115-117, 123-135, 180-182, 217, 219-242, 251-255, 272, 323, 324, 326, 327, 343-356, 360-362, 365-373, 376, 377, 379-385, 389-391, 393 and 394 were rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. The Applicant respectfully traverses the rejection of the pending claims and maintains the arguments presented in the communications filed August 27, 2008, September 28, 2009 and August 19, 2010 by the Applicant. The arguments are incorporated by reference as if fully set forth herein, but all have not been reiterated below for the sake of brevity.

On page 18 of the Office Action, the Examiner states "[n]either Applicants nor the declarations by Dr. Melinda E. Wales, Ph.D. or Dr. James W. Rawlins provide specific arguments regarding this rejection" (referring to the communication filed August 19, 2010 by the Applicant). The Applicant respectfully disagrees. In particular, as acknowledged by the Examiner, the Applicant cited several paragraphs of the specification in the communication filed on August 19, 2010 that describe various active enzymes, including an extensive description of enzymes of E.C. 3.1.8. In addition, the Applicant cited several paragraphs in the communication filed on August 19, 2010 describing various pre-made coatings, elastomers, adhesives, sealants, and waxes and

components thereof to which such enzymes may be admixed to make coatings, elastomers, adhesives, sealants and waxes with enzymatically active enzymes of E.C. 3.1.8. Based on such citations, the Applicant asserted on page 49 of the communication filed August 19, 2010 that the specification conveys to one skilled in the art that the inventor had possession of the claimed subject matter and, therefore, the written description requirement is satisfied for the present claims. Furthermore, both Dr. James Rawlins and Dr. Melinda Wales provide statements in their declarations that the specification provides ample written description to make it clear that the inventor of the claimed subject matter had possession of any type of coating, elastomer, adhesive, sealant, and wax comprising any components and comprising any active enzyme of E.C. 3.1.8 (see, pages 16 and 26 of their respective declarations).

A review of the Examiner's statements under the written description rejection in the Office Action of February 19, 2010 (to which the Office Action of December 14, 2010 refers) notes that the Examiner bases the rejection on an alleged lack of specificity of structure and sequence in the specification for each of the E.C. 3.1.8 enzymes which are encompassed with the pending claims. In addition, the Examiner states that there is an alleged lack of specificity of characteristics or properties of paints in the specification which may comprise an enzymatically active enzyme of E.C. 3.1.8. As set forth above, the Applicant contends such specificity is not needed for one skilled in the art to make and/or use coatings, elastomers, adhesives, sealants, or waxes with an enzymatically active enzyme of E.C. 3.1.8. Furthermore, the Applicant notes above although the description in the specification to what enzymes and specific compositions/components may be used to make the claimed coatings, elastomers, adhesive, sealants and waxes is broad, it is not out of the realm for one skilled in the art to determine based on the ample disclosure in the specification as well as what is readily known in the art. The Applicant further contends that one skilled in the art would recognize the breadth of the claims and further perceive based on the disclosure in the specification that the inventor of the claims had full possession of such breadth.

For at least the reasons set forth above, it is asserted that the specification conveys to one skilled in the art that the inventor had possession of the claimed subject matter and, therefore, the written description requirement is satisfied for the present claims. Accordingly, removal of 35

U.S.C. § 112, first paragraph, written description rejection of the claims is respectfully requested.

Section 102 Rejection

Claims 1, 15-20, 67, 72, 74, 75, 79-89, 94-100, 102, 110-112, 115-117, 123-135, 180-182, 217, 219-223, 234-238, 251-255, 272, 320, 343, 344, 351, 352, 354-356, 360-362, 365-373, 376, 377, 379-385, 389-391, 393 and 394 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,998,200 to Bonaventura et al. (hereinafter referred to as "Bonaventura") as evidenced by a document entitled "Micronized Porous Silica Gel" supplied by W.R. Grace & Co. (referred to herein as "W. R. Grace & Co."). The Applicant respectfully traverses the rejection of the pending claims and maintains the arguments presented in the communications filed August 27, 2008, September 28, 2009 and August 19, 2010 by the Applicant. The arguments are incorporated by reference as if fully set forth herein, but all have not been reiterated below for the sake of brevity. The Examiner responds to some of the arguments in the current Office Action in support of her position to maintain the rejection. Such responses are paraphrased below along with rebuttals by the Applicant.

In the communication filed on August 19, 2010 by the Applicant, the Applicant argues that Bonaventura does not teach or suggest an architectural coating, an automotive coating, a can coating, a chemical agent resistant coating, a camouflage coating, a traffic marker coating, or an aircraft coating as specified for each of the independent claims. In response, the Examiner cites the paragraph bridging columns 5 and 6 in Bonaventura teaching that the method and surfaces taught therein are useful in all types of aquatic environments. In relation to the citing, the Examiner emphasizes examples of aquatic environments, specifically cooling towers, fresh and salt water piping systems, desalination and other filtration system and other aquatic environments which rely upon the intervention of human beings for their creation and maintenance. Based on such disclosure, the Examiner surmises that "the skilled artisan would understand that said paints encompass, at least, architectural paints" (Office Action, page 19). The Applicant respectfully disagrees.

In particular, the same passage of Bonaventura was highlighted on page 51 of the communication filed August 19, 2010 by the Applicant for purposes of emphasizing that none of the coating types recited in the claims refer to coatings specifically formulated for contact with an aquatic environment and, thus, Bonaventura does not teach any of coating types recited in the claims. To substantiate such a position, the Applicant provided a declaration under 37 C.F.R. § 1.132 by Dr. James W. Rawlins, Ph.D. in accompaniment with the communication filed August 19, 2010. In point 22 of the declaration, Dr. James W. Rawlins, a person of skill in the art of coatings and polymer science, declares:

> None of the coating types recited in claims 1, 272, 319, 368, 393 and 394 refer to coatings specifically formulated for contact with an aquatic environment, including the environments noted by Bonaventura *et al.* as being encompassed by the term 'aquatic environment' (i.e., natural bodies of water as well as cooling towers, fresh and salt water piping systems, desalination and other filtration systems containing membrane "surfaces" subject to protection, and other aquatic environments which rely upon the intervention of human beings for their creation and maintenance). Thus, the coating types recited in claims 1, 272, 319, 368, 393 and 394 are distinct from the coatings taught in Bonaventura *et al.* Consequently, claims 1, 272, 319, 368, 393 and 394 exclude the coatings taught in Bonaventura *et al. (Declaration filed on August 19, 2010 by Dr. James W. Rawlins, Ph.D. under 37 C.F.R. § 1.132)*

Thus, the Applicant asserts that one skilled in the art would not understand, much less give credence to a notion that the paints described in Bonaventura encompass, at least, architectural paints as purported by the Examiner.

Further in the communication filed on August 19, 2010 by the Applicant, the Applicant argues the coatings recited in the independent claims of the case are compositionally distinct from the coatings taught in Bonaventura and, thus, Bonaventura fails to anticipate such claims. In response, the Examiner purports that the independent claims fail to recite any structural limitations for the encompassed paints or components therein (Office Action, pg. 19). The Applicant respectfully disagrees. As noted in the communication filed August 19, 2010, the coating types recited in the independent claims of the case each convey their own compositional and material differences as well as structural characteristics and performance differences associated with each type of coating so that the coating material is a composition suitable for

their intended end use applications. Such an assertion is substantiated by Dr. James W. Rawlins, Ph.D., a person of skill in the art of coatings, in point 22 of the declaration referenced above. As such, the coating terms recited in the independent claims impart compositional (i.e., structural) limitations to the claims.

Further in response to the argument that the independent claims of the case are compositionally distinct from the coatings taught in Bonaventura, the Examiner purports on page 20 of the Office Action that Bonaventura teaches the limitations encompassed by many claims of the case, including independent claims 1, 272, 368, 393 and 394. For the reasons set forth above and noted in the communication file August 19, 2010 by the Applicant, the Applicant respectfully disagrees. In particular, it is the Applicant's position that the coating types recited in the claims are distinct from the paints taught in Bonaventura and, thus, the teachings of Bonaventura cannot be encompassed by the claims of the case. In relation to such a position, the Examiner presumes on page 20 of the Office Action, "Since Bonaventura et al teaches the elected subject matter, Applicant's statement that Bonaventura et al does not teach paints encompassed by claims 1, 272, 368, 393 and 394, implicitly argues that claims 1, 272, 368, 393 and 394 do not encompass the elected subject matter. Clarification is requested."

As set forth above, it is well known in the art and it is clearly set forth in the specification that coatings may be differentiated by compositional differences directed by their intended use. Bonaventura substantiates such well known categorization by teaching paints for intended for use in aquatic environments. Although Bonaventura's teachings read on the elected subject matter of a paint comprising an esterase of EC 3.1.8, the teachings are directed to a particular subspecies of paint, which is different than the paint subspecies recited independent claims 1, 393 and 394 as well as the coating subspecies recited in claims 272, 319 and 368. Each of paint subspecies is encompassed by the species of paint and, thus, both Bonaventura and the independent claims of the captioned case can be encompassed by the elected subject matter but not with each other. Thus, the Examiner's conjecture that the Applicant's statement that Bonaventura does not teach paints encompassed by pending claims implicitly argues that the pending claims do not encompass the elected subject matter is erroneous. The basis of the Examiner's confusion appears to be a failure to recognize/understand/accept that coatings may

be subdivided based on coating formulation specific to the environment a coating is intended to be used, even though such an axiom is well known in the art, is well documented in the application and has been set forth in a declaration by one skilled in the art for the captioned case.

In response to the Applicant's arguments and Dr. James Rawlins' declaration that different types of coatings are compositionally distinct from each other, the Examiner states:

> It is acknowledged that [a] skilled artisan would understand that some paints, e.g., wood paints, masonary paints, artist paints have some distinct functional characteristics/requirements. However, as is known in the art, paint formulations are being continuously developed and improved upon … Thus, recitation of use for a paint does not define the structure of functional characteristics of all components that may be found, or not found, in a paint for the recited use. *(Office Action, pg. 20)*

Applicant concurs that paint formulations are continuously being developed. In addition, the Applicant concurs that a mere recitation of use for a paint does not define the structure of functional characteristics of all components that may be found, or not found, in a paint for the recited use. However, the claims of the pending case do not merely specify intended use for a paint. Rather, the claims include terminology which is known in the art of coatings to impart compositional differences to coating materials.

As noted in the communication filed August 19, 2010 and in the declaration by Dr. James Rawlins, although the specific coatings recited in claims 1, 272, 319, 368, 393 and 394 are termed in a manner of their intended application, the terms each convey their own compositional differences and, thus, the terms are not simply differentiated by their intended use alone or by the surfaces to which they will be applied. On the contrary, the terms of the different coating types impart compositional and materials differences so that the coating materials are compositions suitable for their intended end use applications. Those of ordinary skill in the art of coatings are aware and recognize that the end use application forces formulation differences and in turn requires materials, compositional, and performance characteristics associated with each type of coating.

Further in the communication filed on August 19, 2010 by the Applicant, the Applicant argues that there is no basis in W. R. Grace & Co. (which was cited in the Office Action of February 19, 2010 as being evidence to the teachings of Bonaventura) that such coatings or any other coatings described in Bonaventure necessarily include a thermoplastic binder or an antifoamer as presumably purported by the Examiner. In response, the Examiner states "Applicants have acknowledged that Bonaventura et al teach the use [of] paints comprising micronized porous silica gels of WR Grace." (Office Action, page 22). The Applicant respectfully traverses that any such acknowledgment was made. Rather, the Applicant acknowledged that Bonaventura teaches an immobilization matrix formed from micronized porous silica hydrogels, but the immobilization matrix is formed prior to being mixed with the paints described therein. There is no teaching in Bonaventura that the silica hydrogels retain their compositional make-up when the immobilization matrix is formed. Thus, not only does the Applicant refute that the paints taught in Bonaventura include the micronized porous silica gels taught in W. R. Grace & Co., the Applicant asserts it is improper to make such conjecture based on the teachings of Bonaventura and W. R. Grace & Co.

In further response to the arguments made by the Applicant regarding W. R. Grace & Co., the Examiner cites on page 22 of the Office Action a new document entitled "Matting Mechanism" supplied by W.R. Grace & Co. (referred to herein as "Matting Mechanism") referencing the effects of incorporating SYLOID® silica particles within liquid coatings. The Examiner purports Matting Mechanism teaching that the "… micronized porous silica gels are capable of film (mat) formation" (Office Action, pg. 22). Such conjecture is traversed. There is no teaching or suggestion within Matting Mechanism that the silica gels themselves are capable of film formation. Rather, Matting Mechanism merely teaches that the silica gels may be dispersed within a liquid coating to induce micro-roughness to a film as solvent evaporates from the liquid coating.

The Examiner cites an additional new document on page 23 of the Office Action entitled "Water and the glass transition temperature of silicate melts" by Deubener et al. (referred to herein as "Deubener") to provide evidence that silica gels possess glass transition temperatures. Based on such and the fact that thermoplastic binders are capable of film formation and have

glass transition temperatures, the Examiner deduces that the silica gels of W.R. Grace & Co. function as thermoplastic binders. The Applicant refutes the Examiner's convoluted logic. Firstly, glass transition temperatures are not exclusive to thermoplastic materials and, thus, one cannot necessarily assume a material is thermoplastic by such a characteristic. Furthermore, there is no teaching in Bonaventura, W. R. Grace & Co., Matting Mechanism or Deubener that silica gels may function as a coating binder. On the contrary, Bonaventura only references use of silica gels for the formation of an immobilization matrix which is subsequently added into a pre-made coating. One skilled in the art would likely presume the pre-made coating would include a binder already and that the immobilization matrix would not serve to do so. Rather, Bonaventura simply teaches that the immobilization matrix is used to retain an enzyme therein such that it may remain active in the coating. As such, it is not evident by the teachings of Bonaventura, W. R. Grace & Co., Matting Mechanism and/or Deubener that the paints taught in Bonaventura include a thermoplastic binder as purported by the Examiner.

With regard to the Examiner's supposition that W. R. Grace & Co. provides evidence that Bonaventura includes an antifoamer, the Examiner cites an additional new document entitled "SYLOID® Silicas for Water-Borne Coatings" supplied by W.R. Grace & Co. (referred to herein as "SYLOID® Silicas") referencing the silica particles as less foaming. Based on such disclosure, the Examiner concludes that the micronized porous silica gels taught by W. R. Grace & Co. must comprise anti-foaming properties. While a material may be characteristic of low foaming, such a characteristic doesn't necessarily mean the material may function as a material which deters foam as does an anti-foamer. Thus, the Applicant refutes the Examiner's basis as evidence that the silica gels taught by W. R. Grace & Co. are an anti-foamer. Furthermore, as noted above, there is no teaching in Bonaventura that the silica hydrogels retain their compositional make-up when an immobilization matrix is formed. Thus, even if the silica gels taught by W. R. Grace & Co. could be considered anti-foamers, for the sake of argument only, it still is not evident in view of the teachings of Bonaventura and W. R. Grace & Co. that the paints taught in Bonaventura inherently include an antifoamer as purported by the Examiner.

As noted above, the Applicant provided in accompaniment with the communication filed on August 19, 2010 a declaration under 37 C.F.R. § 1.132 by Dr. James W. Rawlins, a person of

skill in the art of coatings and polymer science, regarding the patentability of the pending claims over Bonaventura and the evidence purportedly exhibited in W.R. Grace & Co. In the declaration, Dr. James W. Rawlins declares the different coating types recited in the claims impart compositional differences and one skilled in the art would recognize such based on the recitation of the coating terms. In addition, Dr. James W. Rawlins declares that none of the coating types recited in claims 1, 272, 319, 368, 393 and 394 refer to coatings specifically formulated for contact with an aquatic environment and, thus, the coating types recited in claims 1, 272, 319, 368, 393 and 394 are structurally distinct from the coatings taught in Bonaventura. On page 23 of the Office Action, the Examiner finds points 18-28 and 30 of Dr. Rawlins' declaration not persuasive for the same reasons the arguments presented by the Applicant in the communication filed August 19, 2010 are refuted. In making such a rebuttal, there is no indication that the Examiner has given any weight or even consideration to Dr. Rawlins' statements of facts and beliefs of how one skilled in their respective arts would interpret the teachings of Bonaventura or W.R. Grace & Co. In view of such and the arguments noted above as well as the arguments noted in the communication filed August 19, 2010 by the Applicant, the Applicant reiterates his position that Bonaventura does not anticipate the limitations of the pending claims.

For at least the reasons set forth above, Bonaventura does not anticipate the limitations of independent claims 1, 272, 319, 368, 393 and 394 or any claims dependent therefrom. Accordingly, removal of the 35 U.S.C. § 102(b) rejection in the Office Action is respectfully requested.

Section 103 Rejections

Claims 21-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Bonaventura in view of a paper entitled "*Rational design of organophosphorus hydrolase for altered substrate specificities*," by Di Sioudi et al. (hereinafter referred to as "Di Sioudi") and in further in view of a datasheet for enzymes classified as EC 3.1.8.1 taken from the ExPASy (Expert Protein Analysis System) Proteomics Server provided by the Swiss Institute of Bioinformatics (hereinafter referred to as "ExPASy") or in view of a paper entitled

"*Immobilization of β-Galactosidase for Application in Organic Chemistry Using a Chelating Peptide*" to Piesecki et al. (hereinafter referred to as "Piesecki"). Claims 73, 323 and 324 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Bonaventura in view of datasheets on sodium phosphate dibasic and carbonate-bicarbonate buffer provided from Sigma-Aldrich Co. (hereinafter referred to as "Sigma"). Claims 224-233, 326 and 327 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Bonaventura in view of U.S. Patent No. 4,495,239 to Pusch et al. (hereinafter referred to as "Pusch"). Claim 309 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bonaventura in view of a paper entitled "*The bile acid-inducible baiF gene from Eubacterium sp. strain VPI 12708 encodes a bile acid-coenzyme A hydrolase*" to Ye et al. (hereinafter referred to as "Ye"). Claims 321 and 345-347 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonaventura in view of U.S. Patent No. 5,096,813 to Krumhar et al. (hereinafter referred to as "Krumhar"). Claims 348-350 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonaventura in view of U.S. Patent No. 4,999,306 to Yafuso et al. (hereinafter referred to as "Yafuso").

The Applicant respectfully traverses the rejection of the pending claims and maintains the arguments presented in the communication filed August 19, 2010 by the Applicant. The arguments are incorporated by reference as if fully set forth herein, but have not been reiterated herein for the sake of brevity. The Examiner responds to some of the arguments in the current Office Action stating the arguments are not persuasive for the reasons explained in reference to the rejection under 35 U.S.C 102(b) (Office Action, pg. 25).

For at least the reasons cited above, none of the cited art, taken alone or in combination, teaches or suggests the limitations of independent claims 1, 272, 319, 368, 393 and 394. As such, claims 1, 272, 319, 368, 393 and 394 as well as all dependent claims thereto are patent distinct over the cited art. Accordingly, based on the forgoing, removal of all the § 103(a) rejections is respectfully requested.

CONCLUSION

This response constitutes a complete response to all of the issues raised in the Office Action mailed December 14, 2010. In view of the amendments and remarks herein, Applicants assert that pending claims 1, 15-28, 31-35, 37-39, 43-45, 49-52, 55-63, 67, 69-75, 79-108, 110-112, 115-117, 123-256, 272, 319-362, 365-373, 376, 377, 379-391, 393 and 394 are in condition for allowance. If the Examiner has any questions, comments, or suggestions, the undersigned earnestly requests a telephone conference.

The Commissioner is authorized to charge any fees which may be required, or credit any overpayment, to deposit account no. 50-1085.

Respectfully submitted,

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Customer No. 62754
Date: June 14, 2011